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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 097522,753 03/10/00 **EVANS** SALK1510-3 **EXAMINER** HM22/0629 T STEPHEN E REITER GRAY CARY WARE & FREIDENRICH LLP U HARA, E 4365 EXECUTIVE DRIVE **ART UNIT** PAPER NUMBER SUITE 1600 SAN DIEGO CA 92121-2189 1646 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or pr ceeding.

**Commissioner of Patents and Trademarks** 

06/29/01

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Application No.

09/522,753

Applicant(s)

Examiner

Office Action Summary

Art Unit

Evans et al.

		O'Hara, Eileen	1646	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address				
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.				
aft - If the be - If NO co	sions of time may be available under the provisions of 37 C or SIX (6) MONTHS from the mailing date of this communic period for reply specified above is less than thirty (30) days considered timely.  period for reply is specified above, the maximum statutory mmunication.  e to reply within the set or extended period for reply will, by	cation.  s, a reply within the statutory minimun  period will apply and will expire SIX (6	of thirty (30) days	s will ne mailing date of this
- Any r	eply received by the Office later than three months after the rned patent term adjustment. See 37 CFR 1.704(b).			
Status				
1) 📙	Responsive to communication(s) filed on			•
2a) 🗌	his action is <b>FINAL</b> . 2b) 💢 This action is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.				
Disposit	ion of Claims			
4) 🗶	Claim(s) <u>1-37</u>	is/are	pending in the	application.
4	a) Of the above, claim(s)	is/ar	e withdrawn fro	m consideration.
5) 🗆	Claim(s)		is/are allowed.	
6) 🗆	Claim(s)		is/are rejected.	
7) 🗌	Claim(s)		is/are objected t	0.
8) 💢	Claims <u>1-37</u>	are subject to restric	tion and/or elect	tion requirement.
Application Papers				
9) 🗆	The specification is objected to by the Examiner.			
	The drawing(s) filed on is/are objected to by the Examiner.			
11) 🗌	☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved.			
12) The oath or declaration is objected to by the Examiner.				
Priority under 35 U.S.C. § 119 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).				
a) All b) Some* c) None of:				
1. Certified copies of the priority documents have been received.				
2. Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  *See the attached detailed Office action for a list of the certified copies not received.				
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).				
Attachment(s)				
_	ottice of References Cited (PTO-892)	18) Interview Summary (PTO-413) Paper	No(s)	
_	ntice of Draftsperson's Patent Drawing Review (PTO-948)	19) Notice of Informal Patent Application		
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20) Other:				

Application/Control Number: 09/522723

Art Unit: 1646

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-25, drawn to nucleic acids, vectors, and host cells, classified in class 536, subclass 23.5 and class 435, subclasses 320.1 and 325.
  - II. Claims 26-28, and 31-33, drawn to polypeptides, classified in class 530, subclass 324.
  - III. Claims 29 and 30, drawn to antibodies, classified in class 530, subclass 387.9
  - IV. Claim 34, drawn to a method of screening for agents by detecting DNA expression, classified in class 435, subclass 6.
  - V. Claim 35, drawn to a method of screening for agents by detecting activity of SMRT, classified in class 435, subclass 7.21.
  - VI. Claim36, drawn to a method of modulating transcription, classified in class 514, subclass 2.
  - VII. Claim 37, drawn to a method of detecting a binding agent, classified in class 435, subclass 7.1.
- 2. The inventions are distinct, each from the other because of the following reasons: Inventions I, II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to completely different products having completely different structures and

Application/Control Number: 09/522723 Page 3

Art Unit: 1646

biological functions which are not interchangeable and which require non-cohesive searches and considerations.

- 3. Inventions IV, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to completely different methods each having completely different method steps, using different compositions, and having completely different outcomes. The method of screening for modulators of expression will not identify modulators of activity or binding agents. The method of identifying modulators of a given activity will not provide information regarding DNA expression or binding abilities. The method of identifying binding will not provide information regarding effect on activities or DNA expression. Finally, the method of treatment will not identify agents at all nor will any of the screening methods effectively modulate transcription.
- 4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA may be used in a materially different process, such as the production of polypeptide.

Application/Control Number: 09/522723 Page 4

Art Unit: 1646

5. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be used in materially different method such as to immunize with.

- 6. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be used in materially different method such as to immunize with.
- 7. Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be used in materially different method such as to immunize with.

Art Unit: 1646

- 8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 9. Because these inventions are distinct for the reasons given above and the search required for and single Group is not required for any other Group, restriction for examination purposes as indicated is proper.
- 10. This application contains claims directed to patentably distinct species of the claimed invention defined by different sequence identifiers of nucleic acid and the polypeptide which that nucleic acid encodes. The species are as follows:
  - a. SEQ ID NO: 4 encoding SEQ ID NO: 5
  - b. SEQ ID NO: 6 encoding SEQ ID NO: 7
  - c. SEQ ID NO: 8 encoding SEQ ID NO: 9

Each of these species is completely different having a completely different structure and requiring a completely different search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

d. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 630pm.

The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

Art Unit: 1646

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 28, 2001

YVONNE EYLER, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600